MAY 2 3 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K014193

1. Date of Summary: Dec.12, 2001

2. Submitted by: Princeton BioMeditech Corperation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang, Ph.D., Director

3. Device Name
   Trade Names: Stick: Status Stik™ THC/OPI/COC/MET,
   AccuSign®Stik THC/OPI/COC/MET, AccuStik™ DOA4
   Card: AccuSign® DOA4, Status DS™ DOA4
   Strip: AccuStrip™ DOA4
   Common or Usual Name: Immunoassay for detection of THC, opiates, cocaine, and methamphetamine in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DKE, 91DJG, 91DIO for Enzyme Immunoassay, 91LAG for HPLC)

4. Identification of legally marketed device to which claims equivalence:
   For THC, COC, MET: Status DS™ DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP), k990786
   For OPI: Status DS™ OPI, k981771

5. Device Description: Status Stik™ THC/OPI/COC/MET is simple one step immunochromatographic test for the rapid, qualitative, simultaneous detection of THC, opiates, cocaine, and methamphetamine.

6. Intended Use: Status Stik™ THC/OPI/COC/MET is designed for the qualitative detection of THC at the cutoff of 50 ng/mL 11-nor-Δ^9-THC-9-carboxylic acid, opiates at the cutoff of 2000 ng/mL morphine, cocaine at the cutoff of 300 ng/mL benzoylecgonine, and methamphetamine at the cutoff of 1000 ng/mL d-methamphetamine in human urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use.

7. Substantial Equivalence: Status Stik™ THC/OPI/COC/MET is substantially equivalent to the k990786, Status DS™ DOA 10 for THC, COC, MET and k981771, Status DS™ OPI for OPI. All three products use the same assay principle and are immunochromatographic assays to detect THC, opiates, cocaine and methamphetamine qualitatively. The detecting cutoff levels are the same. The tests demonstrated 100 % correlation when more than 90 specimens for each drug were compared respectively. The difference is Status Stik™

THC/OPI/COC/MET detects four drugs, while Status DS™ DOA 10 detects seven other drugs of abuse in addition to THC, cocaine and methamphetamine, and Status DS™ OPI detects morphine only.

Conclusion: The device is substantially equivalent to the legally marketed devices k990786, Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/BAR/ MTD/TCA/AMP) and k981771, Status DS™ OPI.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K014193

2. Date of Summary: Dec.12, 2001

2. Submitted by: Princeton BioMeditech Corperation
4242 U.S. Route 1, Monmouth Jct., NJ 08852
PHONE 732-274-1000
FAX 732-274-1010
Contact Person: Jemo Kang, Ph.D., Director

6. Device Name
Trade Names: LifeSign® Home Drug Test (THC/OPI/COC/MET)
Common or Usual Name: Immunoassay for detection of THC, opiates, cocaine, and methamphetamine in urine
Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DKE, 91DJG, 91DIO for Enzyme Immunoassay, 91LAG for HPLC)

7. Identification of legally marketed device to which claims equivalence:
For THC, COC, MET: Status DS™ DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP), k990786
For OPI: Status DS™ OPI, k981771

8. Device Description: LifeSign® Home Drug Test (THC/OPI/COC/MET) is simple one step immunochromatographic test for the rapid, qualitative, simultaneous detection of THC, opiates, cocaine, and methamphetamine.

6. Intended Use: LifeSign® Home Drug Test is designed for the qualitative detection of THC at the cutoff of 50 ng/mL 11-nor-Δ^9-THC-9-carboxylic acid, opiates at the cutoff of 2000 ng/mL morphine, cocaine at the cutoff of 300 ng/mL benzoylecgonine, and methamphetamine at the cutoff of 1000 ng/mL d-methamphetamine in human urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use. This test is intended for use in the home to assist in preventing drug abuse.

7. Substantial Equivalence: LifeSign® Home Drug Test is substantially equivalent to the k990786, Status DS™ DOA 10 for THC, COC, MET and k981771, Status DS™ OPI for OPI. All three products use the same assay principle and are immunochromatographic assays to detect THC, opiates, cocaine and methamphetamine qualitatively. The detecting cutoff levels are the same. The tests demonstrated 100 % correlation when more than 90 specimens for each drug were compared respectively. The difference is that LifeSign® Home Drug Test detects four drugs, while Status DS™ DOA 10 detects seven other drugs of abuse in addition to THC, cocaine and methamphetamine, and Status DS™ OPI detects morphine only.

8. Consumer Study: In a consumer study, LifeSign® Home Drug Test (THC/OPI/ COC/ MET) showed over 95% overall accuracy.

Conclusion: The device is substantially equivalent to the legally marketed devices k990786, Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/BAR/ MTD/TCA/AMP) and k981771, Status DS™ OPI. The product is safe in the hands of the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2002

Jemo Kang, Ph.D.
Director
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, NJ 08852-1905

Re: k014193
Trade/Device Names: LifeSign®Home Drug Test (THC/OPI/COC/MET)
Status Stik™ THC/OPI/COC/MET, AccuSign®Stik THC/OPI/COC/MET,
AccuStik™ DOA4,AccuSign® DOA4, Status DS™ DOA4,
AccuStrip™ DOA4
Regulation Numbers: 21 CFR 862.3610; 21 CFR 862.3870; 21 CFR 862.3250;
21 CFR 862.3650
Regulation Names: Methamphetamine test system; Cannabinoid test system; Cocaine and cocaine metabolite test system; Opiate test system
Regulatory Class: Class II
Product Codes: MVO; DJC; LDJ; DIO; DJG
Dated: April 9, 2002
Received: April 10, 2002

Dear Dr. Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K 014193

Device Name: Status Stik™ THC/OPI/COC/MET, AccuSign®Stik THC/OPI/COC/MET, AccuStik™ DOA4, AccuSign® DOA4, Status DS™ DOA4, AccuStrip™ DOA4

Indications For Use:

Immunoassay for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine in urine to assist in screening of drugs of abuse. For *in vitro* Diagnostic Use

The detection cutoff concentrations are as follows:

THC	11-nor-Δ^9-THC-9-carboxylic acid	50 ng/ml
OPI	Morphine	2000 ng/ml
COC	Benzoylecgonine	300 ng/ml
MET	D-Methamphetamine	1000 ng/ml

Trade Names for each device format

Stick: Status Stik™ THC/OPI/COC/MET, AccuSign®Stik THC/OPI/COC/MET, AccuStik™ DOA4

Card: AccuSign® DOA4, Status DS™ DOA4

Strip: AccuStrip™ DOA4

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014193

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:____

Prescription Use: X OR Over The Counter Use: ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K014193

Device Name: LifeSign® Home Drug Test (THC/OPI/COC/MET)

Indications For Use:

Immunoassay for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine in urine to assist in screening of drugs of abuse samples at home or work places. For *in vitro* Diagnostic Use. The detection cutoff concentrations are as follows:

THC	11-nor-Δ^9-THC-9-carboxylic acid	50 ng/ml
OPI	Morphine	2000 ng/ml
COC	Benzoylecgonine	300 ng/ml
MET	D-Methamphetamine	1000 ng/ml

Stan Coggin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014193

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:____

Prescription Use:____ OR Over The Counter Use: _X__

(Per 21 CFR 801.109)

(Optional Format 1-2-96)